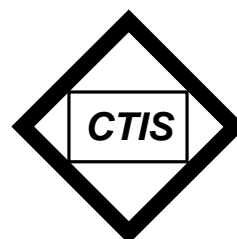


Clinical Data Update System (CDUS) v3.0 Release 3

Notice of Modifications

July 20, 2005

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Editorial Clarifications and Modifications

The revisions cited below were made to the *CDUS Instructions and Guidelines V3R3* to remove references to the Cooperative Group special response requirement. The following modifications were made:

Section 1.3.2 COMPLETE CDUS DATA SET (paragraph 3)

From:

The complete report should be submitted quarterly (Cooperative Groups may submit Phase 2 response data within 6 weeks of the completion of each stage of the study. Response data for all Phase 1 trials and non-Group Phase 2 trials should be submitted on a quarterly basis.

To:

The complete report should be submitted quarterly. Response data for all Phase 1 trials and Phase 2 trials should be submitted on a quarterly basis.

Section 1.3.3.1.3. PHASE 2 TRIALS THAT INCLUDE DCTD-SUPPLIED INVESTIGATIONAL AGENTS

From:

A Complete CDUS Data Set report is required (all CDUS data elements except Phase 1 endpoints). Investigators should submit the Complete CDUS Data Set report to CTEP on a quarterly basis. Response data for all non-Cooperative Group Phase 2 trials should be submitted quarterly. Response data for Cooperative Group Phase 2 trials may be submitted within 6 weeks of the completion of each stage of the study.

To:

A Complete CDUS Data Set report is required (all CDUS data elements except Phase 1 endpoints). Investigators should submit the Complete CDUS Data Set report to CTEP on a quarterly basis. Response data for all trials shall be submitted quarterly.

Section 2.2.4. RESPONSE OF PATIENT'S MALIGNANCY (footnote)

Requested for trials assigned to Complete CDUS reporting, e.g., Phase 1 and 2 trials with DCTD-supplied investigational agents⁸. It is not required for other studies.

⁸Response data for all Phase 1 trials and all non-Cooperative Group Phase 2 trials should be submitted quarterly. Response data for Cooperative Group and CCOP Research Base Phase 2 trials may be submitted within six weeks of the completion of each stage of the study.

Footnote (8) was removed from this section.